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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,753	10/29/2001	Yasuhiro Sakai	3029-74	7298

7590 01/27/2005

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/005,753	<b>Applicant(s)</b> SAKAI ET AL.	
	<b>Examiner</b> Francisco C. Prats	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 20-27, 30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30 and 31 is/are allowed.
- 6) ☒ Claim(s) 20-24, 26 and 27 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1651

#### **DETAILED ACTION**

The amendment filed October 29, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 20-27, 30 and 31 are pending and are examined on the merits.

#### ***Election/Restrictions***

Applicant's election of the species wherein the nitrite reducer is sulfamic acid, in Paper No. 5, filed June 9, 2003, is again acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). As noted in the previous office action, because a composition comprising a polymethine dye, sulfamic acid as a nitrite reducer (the elected species) and a buffer for maintaining an acidic pH is considered free of the prior art, examination has been extended to other species within the Markush group of claim 21.

***Claim Rejections - 35 USC § 103***

Claims 20-24, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizukami et al (EP 0 882 983 A2) in view of Kohnert et al (U.S. Pat. 5,366,730).

Mizukami discloses processes whereby a reagent comprising a polymethine dye and a quaternary ammonium surfactant, at a pH ranging from 4.5 to 11, is used to differentially stain leukocytes. See pages 3 and 4. Mizukami differs from the claims failing to disclose the inclusion in the reagent of a substance capable of reducing nitrite ions.

However, Mizukami clearly discloses the desirability of using a buffer in the composition. See, e.g., page 3, lines 42-44. One of ordinary skill in the art clearly would have recognized that ascorbic acid was suitable for use as a buffer within the pH range (4.5 to 11) described by Mizukami as being useful for the staining reagent disclosed therein. For example, Kohnert, in Table 1 at column 3 discloses an ascorbic acid/NaOH buffer for maintaining t-PA at pH 6.0. Recognizing the suitability of ascorbic acid as a buffer in Mizukami's staining reagent, the artisan of ordinary skill would have been motivated to have included it in Mizukami's staining reagent. Thus, the artisan of ordinary skill would have been motivated to have included a compound which meets the claim limitations of being

Art Unit: 1651

both a buffer for maintaining an acidic pH, and being a nitrite ion reducer. A holding of obviousness over the cited claims is therefore required.

### ***Response to Arguments***

All of applicant's argument has been fully considered but is not persuasive of error. Regarding the remaining § 103(a) rejection, applicant initially urges that Mizukami does not disclose the use of the reagent disclosed therein in the staining of bacteria. However, it is respectfully pointed out that applicant's claims are not directed to methods of staining bacteria. Rather, applicant's claims are directed to compositions. Thus, applicant's argument in this regard is not directed to any claim-recited limitation or process step. Moreover, as long as the prior art provides motivation for assembling the claimed ingredients in a single composition, that composition must be considered obvious under § 103(a), even if the prior art's intended use of the composition is different than applicant's.

Applicant similarly argues that the Kohnert reference is not directed to staining bacteria, or reducing nitrite ions in bacteria. Again, however, applicant's claims are not directed to methods of staining bacteria, or reducing nitrite ions in

Art Unit: 1651

bacteria. Rather, applicant's claims are directed to compositions comprising a polymethine dye, an acidic buffer, and an agent which reduces nitrite ions. Kohnert is cited for the proposition that at least one of the claimed nitrite-reducing agents, ascorbic acid, is suitable for use as a buffer at a pH which is disclosed in Mizukami as being useful in staining leukocytes with polymethine dye. Thus, the cited prior art demonstrates that the claim-recited nitrite-reducing compounds include a compound which serves both as buffer and nitrite reducer.

In response to applicant's argument that the Mizukami and Kohnert references are directed to nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Mizukami discloses that an acidic buffer is useful in the leukocyte staining polymethine dye-containing compositions disclosed therein. Kohnert establishes that ascorbic acid is a suitable buffer for use within the pH range set forth by Mizukami. Thus, because Kohnert establishes that ascorbic acid was known in the art to

Art Unit: 1651

be useful as a buffer at the buffered pH range described by Mizukami, Kohnert is clearly pertinent to the problem faced by Mizukami. The obviousness rejection must therefore be maintained.

Claims 30 and 31 are allowed. Claim 25 is objected to as depending from a rejected claim.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

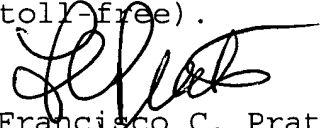
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C. Prats  
Primary Examiner  
Art Unit 1651

FCP